

Remarks

An Office Action was mailed in the above-captioned application on November 30, 2006. Claims 69-75 were pending in the application. Claims 69-75 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

The specification has been amended to restore the sentence stating that SEQ ID NO:63 represents the complement of SEQ ID NO:61.

A new sequence listing has been submitted in which the typographical errors present in originally submitted SEQ ID NO:61 and SEQ ID NO:62 have been corrected.

New claims 82-84 have been submitted.

Claims 69 and 71 have been amended to specify the claimed protein and polypeptide, respectively, comprise or consist, respectively, of specific SEQ ID NO's.

New claims 82 and 83 are drawn to kits comprising the claimed protein and polypeptide. Support for such kits can be found in the specification, for example, on page 52, lines 22-26, through page 54, lines 1-5.

New claim 84 is drawn to a protein comprising an amino acid sequence encoded by the a nucleotide sequence fully complementary to SEQ ID NO:63. Support can be found in Claim 69.

I. Statement of Substance of Interview

On February 8, 2007, Applicant's agent, Richard J. Stern, conducted a telephonic interview with Examiner Steadman to discuss the rejection of pending claims 69-75. The Applicants' agent thanks the Examiner for the courtesy extended during the interview.

During the interview Applicant's agent and Examiner Steadman discussed the fact that while the specification states that SEQ ID NO's 61 and 63 are fully complementary, an alignment of these two sequences reveals that they are not fully complementary. In particular, SEQ ID NO's 61 and 63 are complementary at all positions with the exception of position 329 (using the numbering of SEQ ID NO:61). Applicant's agent explained that this discrepancy was the result of a typographical error introduced into SEQ ID NO:61 during preparation of the Application. The agent further explained that while SEQ ID NO:62 also contains an error, since it is the translation product of SEQ ID NO:61, SEQ ID NO:63 is error-free. To correct the noted

discrepancy Applicants agent proposed correcting the error by submitting a new SEQ ID listing in which SEQ ID NO:61 is corrected, making it fully complementary to the current SEQ ID NO:63; SEQ ID NO:62 would also be corrected as part of this submission.

The Examiner agreed that the specification seemed to support the idea that SEQ ID NO's 61 and 63 were intended to be complementary. The Examiner noted that there did not appear to be any reason favoring the correction of one sequence over another (i.e., SEQ ID NO:61 or SEQ ID NO:63) and requested Applicants representative submit arguments in writing for consideration. The Examiner further stated that if there were any evidence, such as priority cases, publications, etc, which supported SEQ ID NO:63 as the correct complement of the intended SEQ ID NO:61, such evidence would be helpful in considering the agents proposal. The interview concluded with no agreement being reached on the instant claims and with the understanding Applicants would be submitting a Response to the currently outstanding Office Action.

II. Corrected sequence listing

As has been noted by the Examiner, there is a discrepancy between the specification and the flea spit I (fspI) protein sequences submitted with the original Sequence Listing. Specifically, the specification on page 94, lines 20-22, states that SEQ ID NO:61 and SEQ ID NO:63 are complementary. However, an alignment of SEQ ID NO:61 and SEQ ID NO:63 shows a mismatch at a single position (position 329 of SEQ ID NO:61 and position 679 of SEQ ID NO:63, shown in bold).:

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SEQ ID NO:63
SEQ IS NO:61 (sequence reversed for alignment purposes)

TTTTTTTTTT TTTTTTTTTT TTATATTAAG CATAACAGATG CGCATTATT CATTACAATA
AAAAAAAAAAA AAAAAAAAAA AATATAATTG GTATGTCTAC GCGTAAATAA GTAATGTTAT

TTTATATATT TGAAAATATT CGGGTATTAT GTATGAAACA TTTTGCAAC TTTTTAGAA TTAAATAATC
AAATATATAA ACTTTATATAA GCCAATAATA CATACTTGT AAAACGTTG AAAAATCTT AATTATTAG

CACTACTTTT TTATATATAA CAATACCCCA ATTCGTCTCT GTCTACAATT TTATATTAAT TTTTATATAA
GTGATGAAAA AATATATATT GTTATGGGGT TAAGCAGAGA CAGATGTTAA AATATAATTA AAAATATATT

TAAGAGTAAT ACCAAGACAA TATTAGGAA GAAAATATGT AGTAAATCCA GTAAGGGTTT CCATGCAATT
ATTCTCATTA TGGTTCTGTT ATAAATCCTT CTTTATACA TCATTAGGT CATTCCAAA GGTACGTTAA

TTGCACTTAT TTAGTATATC TAATGTAGCT TCTAAATGCT TTGTTCAATA TAACTTACGT ATTTGAATAT
AACGTGAATA AATCATATAG ATTACATCGA AGATTTACGA AACAAAGTTAT ATTGAATGCA TAAACTTATA
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TTTATACACA ACAAAATAAT CTAAGTTAGT TTCTAATATC AAGATATTCT AGAAAAACGC CTTATATTTG
AAATATGTGT TGTTTATTA GATTCAATCA AAGATTATAG TTCTATAAGA TCTTTTGCG GAATATAAAC

AAAAAAACAT TCGAAATTAC ACAACTAATT TATGTGTTAT ATTGTTCAT AATTATAAGC CACTTTCTA
TTTTTTGTA AGCTTAATG TGTTGATTAA ATACACAATA TAACAAGTAT TTAATATTG GTGAAAAGAT

ATATGTGATG GGATAACTAA TAACTATAAC AATTTATTAA TTATAATTAT TATTTATTTT TTGGTCGACA
TATACACTAC CCTATTGATT ATTGATATTG TAAATAAAAT AATATTAAATA ATAATAAAAAA AACAGCTGT

ATAACAAAAG TTTCCATCAC ATCCAGCATC ATTTCCACCA CGACATTTT CTTGCAATG TTTTTGCAT
TATTGTTTC AAAGGTAGTG TAGTCGTAG TAAAGGTGGT GCTGTAAAAA GAAACGTTAC AAAAAACGTA

TTGGAATCTT CATTGGTCTC TGAATTTTT AGTTGCAAAT TATTTGGAAT TGCTAATTGT TGTCGATATG
AACCTTAGAA GTAACCAGAG ACTTAAAAAA TCAAACGTTT ATAAACCTAA ACGATTAACA ACAGCTATAC

GAACATTTTC CGTAGGACGA GAATCTTGT TATTGGGATC TTTGCATTCT TTGCTTACTT TCCAATCAGG
CTTGATAAAG GCATCCTGCT CTTAGAAACA ATAACCCTAG AAACGTAAGA AACGAATGAA AGGTTAGTCC

ACCTAAATTA CTTGGCCTGC TGCAGTAGCA AATATTGCCA TCACAAGCTC CTCTATAACC TTTGCAAAC
TGGATTAAAT GAACCGGACG ACGTCATCGT TTATAACGGT AGTGTGAG GAGATATTGG AAACGTTGA

TTTTGCAAAT TTTCATACA TTTTCTTTC TCTTGATTG TATGTGGTTT ATCTCGTATT AATTTGCAAAT
AAAAACGTTT TAAAGTATGT AAAAAGAAAG AGAACTAAAC ATACACCAAA TAGAGCATAA TTAAACGTTT

TATTTGGAT TTTAACTTGT TGGCCTTTT GAATTATTG ATCGAGTTT CTATCTTGAT TTTTCCACC
ATAAAACCTA AAATTGAACA ACCGGAAAAA CTTAATAAAC TAGCTAAAA GATAGAACTA AAAAGGTGG

TGATGTACAT TTTTATTAA CTTTCCA
ACTACATGTA AAAATAATT GAAAGGT

SEQ ID NO:61 contains an adenine position 329. If SEQ ID NO:61 and SEQ ID NO:63 were complementary, as stated in the specification, SEQ ID NO:61 would contain a thymidine at this position to be complementary to nucleotide 679 of SEQ ID NO:63; or SEQ ID NO:63 would contain a thymidine at the position 679 in order to be complementary to nucleotide 329 of SEQ ID NO:61.

As was discussed with the Examiner in the telephonic interview conducted on February 8, 2007, and in the office action response dated September 9, 2005, the above-referenced discrepancy is the result of a typographical error introduced into SEQ ID NO:61 during prosecution of the parent Application, U.S. Application Serial No. 09/171, 156, now U.S. Patent 6,368,846. Furthermore, since SEQ ID NO:62 was electronically generated from SEQ ID NO:61, the typographical error resulted in a different amino acid being assigned at position 110 of SEQ ID NO:62. As has been previously stated, both the Applicant and Applicants' agents were unaware of these changes at the time of submission.

In order to correct this discrepancy, Applicants have submitted a revised Sequence Listing in which position 329 of SEQ ID NO:61 has been changed from an adenine to a thymidine. Thus, SEQ ID NO:63 is now the complement of SEQ ID NO:61. As noted in the rejection, the

complement of SEQ ID NO:63 encodes SEQ ID NO:62. As a result of changing SEQ ID NO:61 to be the complement of SEQ ID NO:63, the codon spanning nucleotides 328-330 now encodes an isoleucine instead of an asparagine. Consequently, SEQ ID NO:62 has been changed to accurately reflect the translation product of amended SEQ ID NO:61; specifically position 110 of SEQ ID NO:62 now contains an isoleucine.

As has been acknowledged by the Examiner, it is clear from the specification that Applicants intended SEQ ID NO's 61 and 63 to be complements of each other (see, for example, page 94, lines 8-22). Thus one of these sequences needs to be amended in order to make them complementary. Applicants have amended SEQ ID NO's 61 and 62 based on the sequence of SEQ ID NO:63, which has been the complement of the fspI coding sequence, and which has been the correct sequence, as of the earliest filing date.

Furthermore, in support of their position that SEQ ID NO:63 is the intended fspI sequence, Applicants have submitted, as Exhibit A, a copy of the NCBI GenPept Record for Accession No. AAC69105, which contains the fspI sequence information submitted by Applicants to GenPept. An alignment (see Exhibit B) of the fspI sequence from the GenPept Record with that of SEQ ID NO:62 shows that the amino acid in the GenPept fspI protein sequence corresponding to position 110 of SEQ ID NO:62 is an isoleucine. (For the Examiner's convenience, the amino acid positions being discussed have been outlined in the alignment).

Finally, the GenPept Record also shows that the sequence information was submitted for review on July 10, 1996 (see the bolded date under "Journal" in the Record), which is prior to the filing date of the PCT application to which the US application claims priority. Therefore, it is clear from the GenPept submission that, at the time of filing, Applicants knew that the amino acid encoded by the codon at position 328-330 of SEQ ID NO:61 (amino acid 110) was an isoleucine. This is further supported by the fact that the protein encoded by the reverse complement of SEQ ID NO:63 also has an isoleucine at position 110 (see Exhibit B). Applicants believe the evidence clearly supports that SEQ ID NO:61, and its translation product represented by SEQ ID NO:62 are in error. In view of this, Applicants request the Examiner enter the newly submitted Sequence Listing containing the corrected versions of SEQ ID NO:61 and 62 into the Application.

III. Specification/Informalities

The Examiner has objected to amendments that removed the statement on page 94, lines 20-22, of the specification, which stated that SEQ ID NO:63 is the complement of SEQ ID NO:61. Specifically, the Examiner states that such amendment introduces new matter in that it breaks the previously disclosed complementary relationship between SEQ ID NO:61 and SEQ ID NO:63 such that these sequences are no longer required to be interrelated and instead are independent nucleic acids. The rejection states that the complementary relationship is supported by the sequences of SEQ ID NO:61 and 63 as originally filed, wherein SEQ ID NO:63 is the complement of SEQ ID NO:61. Applicants respectfully points out in the sequences as originally filed, there was a mismatch between SEQ ID NO:63 and SEQ ID NO:61, which resulted in SEQ ID NO:63 not being the complement of SEQ ID NO:61, as explained in detail above.

Applicants have submitted a replacement paragraph for lines 8-22 on page 94. The replacement paragraph restores the sentence which states that SEQ ID NO:63 is the complement of SEQ ID NO:61, as was stated in the original specification. Furthermore, SEQ ID NO:61 has been amended so that it now accurately represents the complement of SEQ ID NO:63, and SEQ ID NO:62 has been similarly amended. Applicants believe these amendments obviate the Examiners objection as explained in detail below.

IV. Rejections Under 35 U.S.C. § 112, first paragraph (written description)

The Examiner has rejected claims 69-75 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003).

Specifically the Examiner states that since the previous amendment severed the relationship between SEQ ID NO's 61 and 63 (and thus SEQ ID NO:62), the specification fails to support a polypeptide encoded by the complement of SEQ ID NO:63 wherein the polypeptide is other than SEQ IS NO:62.

Applicant respectfully traverses this rejection. Applicants note the specification has been amended restoring the relationship between SEQ ID NO's 61, 62 and 63. Additionally, SEQ ID NO:61 has been amended to correct the obvious typographical error at position 329, and is now the complement of SEQ ID NO:62. SEQ ID NO:62 has been similarly amended to reflect a polypeptide encoded by SEQ ID NO:61. Further, the claims have been amended to specify the claimed protein and polypeptide comprise, or consist of, SEQ ID NO:62.

Applicants submit that the complement of SEQ ID NO:63 and the protein encoded by the complement of SEQ ID NO:63 is included in and sufficiently described by the present specification. The specification provides, at page 11, line 14, to page 12, line 5: “A nucleic acid sequence complement of any nucleic acid sequence of the present invention refers to the nucleic acid sequence of the nucleic acid strand that is complementary to (i.e., can form a complete double helix with) the strand for which the sequence is cited. . . As such, nucleic acid molecules of the present invention, which can be either double-stranded or single-stranded, include those nucleic acid molecules that form stable hybrids under stringent hybridization conditions with either a given SEQ ID NO denoted herein and/or with the complement of that SEQ ID NO, *which may or may not be denoted herein*. Methods to deduce a complementary sequence are known to those skilled in the art.” (emphasis added). Thus, the present specification describes the complement of SEQ ID NO:63.

Furthermore, the specification describes compositions in which an “ectoparasite saliva protein comprises at least a portion of an amino acid sequence, wherein said portion is encoded by a nucleic acid molecule that hybridizes under stringent hybridization conditions with . . . SEQ ID NO:63 . . . Such a nucleic acid molecule includes the complement of SEQ ID NO:63 and the protein therefore includes a protein encoded by the complement of SEQ ID NO:63. As noted above, this is a polypeptide that differs from original SEQ ID NO:62 in that position 110 contains an isoleucine rather than an asparagine.

. Applicants submit therefore that the original specification and sequence listing fully support the amendments to the specification and SEQ ID NOs 61 and 62. Applicants believe these amendments obviate the Examiners objection. Reconsideration is respectfully requested.

V. Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner has rejected claims 69-75 as under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows. Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Specifically the Examiner states that the specification fails to enable a polypeptide encoded by the complement of SEQ ID NO:63, particularly since such a polypeptide is a variant of SEQ ID NO:62.

Applicants note the specification has been amended restoring the relationship between SEQ ID NO's 61, 62 and 63. Additionally, SEQ ID NO:61 has been amended to correct the obvious typographical error at position 329, and is now the complement of SEQ ID NO:62. SEQ ID NO:62 has been similarly amended to reflect a polypeptide encoded by SEQ ID NO:61. Further, the claims have been amended to specify the claimed protein and polypeptide comprise, or consist of, SEQ ID NO:62.

Additionally, as noted above, the present specification describes and enables the complement of SEQ ID NO:63 and the protein encoded by the complement of SEQ ID NO:63.

Applicants believe these amendments obviate the objection. The original specification and sequence listing fully enable the current claims, as explained in detail above. In view of this support, Applicant requests reconsideration of the rejection under 35 U.S.C. § 112, first paragraph for lack of enablement.

Conclusion

Applicants believe the instant claims to be in condition for allowance. In light of the amendments and remarks above, Applicants request the withdrawal of all rejections and solicit allowance of instant claim set. This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970. The Examiner is invited to contact the undersigned should any issues remain.

Respectfully submitted,

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